K072172

MAQUET

Special 510(k): Device Modification: Jostra Pediatric Arterial Cannulae

510(k) SUMMARY

AUG 31 2007

SUBMITTER:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Katrin Schwenkglenks Phone: (011) 49 7478 921- 151 Fax: (011) 49 7478 921- 400
DATE PREPARED:	July 31, 2007
DEVICE TRADE NAME:	Jostra Pediatric Arterial Cannulae
COMMON/USUAL NAME	Arterial Cannulae
CLASSIFICATION NAME	Cardiopulmonary bypass vascular catheter, cannula or tubing
PREDICATE DEVICES OR LEGALLY MARKETED DEVICES	Jostra Pediatric Arterial Cannulae

DEVICE DESCRIPTION / INDICATONS FOR USE STATEMENT

The Jostra Pediatric Arterial Perfusion Cannulae are designed to be used as perfusion cannulae to return arterial blood from the extracorporeal circuit to the patient during cardiopulmonary bypass up to 6 hours or less.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

Jostra Pediatric Arterial Cannulae are identical to the originally cleared Jostra Pediatric Arterial Cannulae, with the only exception that the Jostra Pediatric Arterial Cannulae uses a different material for the white depth markings. Besides this difference the devices are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology.

RISK ANALYSIS

The risk analysis method used to assess the impact of the modification was done acc. to the logic of a Failure Modes and Effects Analysis (FMEA). The design verification tests were performed as a result of this risk analysis assessment.

All possible risks for the user and the patient related to the design change (material change) have been assessed by evaluation or testing acc. to the risk analysis for the Pediatric Arterial Perfusion Cannulae. The following hazards have been addressed:

General hazards related to

- biocompatibility

Hazards related to manufacturing

- adhesiveness of the position marker

The evaluation and test results do not show any kind of risk potential for the user and/or the patient. Based on the test results and evaluation the Pediatric Arterial Perfusion Cannulae are safe and effective for its intended use and are substantially equivalent to the named predicate device. The modification does not alter the fundamental scientific technologies of the Pediatric Arterial Perfusion Cannulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K072172
Jostra Pediatric Arterial Perfusion Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: July 31, 2007
Received: August 6, 2007

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072172

Device Name: Jostra Pediatric Arterial Perfusion Cannulae _____

Indications for Use:

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072172

(Posted November 13, 2003)